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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/019,563 | 07/01/2002 | Jan Otto Solem | JM-050 CON | 8701 |
| 30452 | 7590 | 08/23/2005 | EXAMINER | |
| EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614 | | | GHERBI, SUZETTE JAIME J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/019,563 | SOLEM ET AL. |
| | Examiner | Art Unit |
| | Suzette J. Gherbi | 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 June 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11-13, 15-21, 23, 25-27, 30-32, 34-36, 39, 40 and 42-64 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 11-13, 15-19, 21, 31 and 51-64 is/are allowed.
 6) Claim(s) 23, 25-27, 30, 32, 34-36, 39, 40 and 42-50 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 10/019,563.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

1. Applicant's amendment dated 6/8/05 has been received in application serial number 10/019,63. Claims 22, 24, 28-29, 33, 37-38, and 41 have been canceled.

Priority

2. Applicant's Oath/Declaration states that Swedish patent 9902455-6 filed **6/29/99** is priority. It is requested that a copy of this dated reference be provided for review.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Buchanan *Vet Surg.* 199827 (3):182-93 *Circumferential suture of the mitral annulus for correction of mitral regurgitation in dogs.* Buchanan discloses the invention as claimed noting figure 2 comprising: A method of treating dialated cardiomyopathy of a heart by providing a constriction device having a first state adaptable for delivery into a coronary sinus of the heart; advancing the constriction device from the right atrium into the

coronary sinus of the heart until the constriction device at least partially encircles the mitral valve of the heart and transferring the device to a second state for pressing the coronary sinus against the mitral valve annulus see page 184-185 Guidewire and Catheter Insertion; PSS Passage through the Right Atrium.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 23, 25-27, 30, 32, 34-36, 39-40 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran 5,817,126 in view of Orth et al. 5,591,197. Imran discloses a resilient member (col. 2, lines 62-63 nitinol) having a cross section which *is capable of being received in the coronary sinus of the heart* having a longitudinal dimension; wherein the resilient member shortens along the longitudinal axis. Orth et al. teaches an expandable stent with projecting barbs noting figure 7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the elongate device of Imran and attach the barbed stents Orth et al. to the ends of Imran in order to provide a device which shortens and anchors

and fits into the coronary sinus and because it is self expanding/nitinol the device of Imran is capable of exerting an inward force after expansion on the mitral valve for constricting the mitral valve annulus (see cited Alferness et al. 6,908,478 for the conception of this obviousness).

Allowable Subject Matter

7. Claims 11-13, 15-19, 21, 31, 51-64 are allowed however, it is strongly suggested with regards to claims 11 to add the wording "configured to press" and to claim 13 configured to be maneuvered to the functional language of the claims. This was done for example in claim 31 and this language further clarifies what the structure must do/function.

Response to Arguments

8. Applicant's arguments and amendments with respect to the claims and the prior art Mehra reference 5,170,802 have been considered but are moot in view of the new ground(s) of rejection given above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.
12. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi
09 August 2005